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Technical and Financial

Hypoxia, Monitoring, and Mitigation System

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Submitted By

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14. ABSTRACT The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report. The program consists of two baseline tasks and three optional task. Work has been started on Task 1. Optional Tasks 3, 4 and 5 have not been exercised. An initial system block diagram has been created as well as selection of a target microprocessor. Both algorithms developed under Phase I of HAMS (Parametric and Neurological State Models) remain viable for use in this follow-on effort. We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.					
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1.0 Summary

This quarterly progress report discusses the technical and financial program status for the period of September 2014 through December 2014. This is the first quarterly report on the program.

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report.

The program consists of two baseline tasks and three optional task:

1. Initial Prototypes
2. Design and Development Evolution
3. *Production Ready HW/SW (Option)*
4. *Preliminary Human Testing of SpO2 Sensor and Electronics (Option)*
5. *Final Human Testing of SpO2 Sensor and Electronics (Option)*

Work has been started on Task 1. Optional Tasks 3, 4 and 5 have not been exercised.

Initial work has been concentrated on finding advanced sensors to assist in laboratory investigation for verification/validation work and potential use in the CASEVAC applications. Also a custom pulse-ox has been pursued to optimize the sensor and electronics for the upper arm location. An initial system block diagram has been created as well as selection of a target microprocessor. Capabilities for the system include: WiFi, Accelerometer, ECG, Pressure (altitude), Temperature, Pulse-ox, micro-SD and USB. Enclosure design concepts have been started and will initially be leveraged from work done on Hammerhead as a baseline.

Both algorithms developed under Phase I of HAMS (Parametric and Unconsciousness Models) remain viable for use in HAMS II. We have begun the process of determining the best way to use these as we move forward. The Unconsciousness Model has morphed into more of a Neurological State Model. An analysis of NIRS and SpO2 data provided by Dr. Shender from an altitude chamber study was completed. This included running the Neurological State Model predictions using the SpO2 data with promising results for higher altitudes (18,000 and 25,000 feet). The NIRS data produced expected in regional oxygen levels as did the SpO2 data. The SpO2 data produced a wider dynamic range. NIRS still seems to suffer from a return to pre-exposure baseline.

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

2.0 Introduction

Special Notice 14-SN-0002 outlined a research thrust entitled “Hypoxia Monitoring, Alert and Mitigation System” (HAMS) that was launched under the ONR BAA 14-001 Long Range Broad Agency Announcement (BAA) for Navy and Marine Corps Science and Technology. The primary technology areas of interest for full system development over the lifetime of the program are 1) detection/prediction algorithm, 2) sensing suite, 3) warning modalities, and 4) modes of mitigation. This Special Notice is a follow on to Special Notice 13-SN-0003, published in November 2012. Overall, HAMS must be compatible with multiple operational environments. The intent is to develop a modular prototype, with capabilities for 1) ground troops at altitude and 2) CASEVAC. The team of Athena GTX (Athena) and Criterion Analysis Incorporated (CAI) collaborated, proposed and won an award under this effort.

This quarterly progress report discusses the technical and financial program status for the period of September 2014 through December 2014. It is intended to inform the Program Officer and Administrative Contracting Officer of the technical and financial progress of the HAMS program. This is the first quarterly report on the program.

The program initially launched via Special notice 13-SN-0003 concentrated only on algorithm development. Now this follow-on effort will develop the hardware necessary to implement HAMS. In addition, more data to refine the algorithms and data analysis approaches will be gathered. Sensors which detect SpO2, pulse/pulse rate, ECG, and skin temperature will be researched and evaluated for integration feasibility with a tactile vibrator for alerting the user to the suspicion of growing hypoxia. Novel and non-traditional sensor locations and technologies will be investigated as they impact data and algorithm design issues, and advanced signal processing techniques applied, and compared in this program for extensive technology leveraging.

The goal is to provide optimal protection of military personnel and equipment via intelligent monitoring and adaptive modeling that accounts for individual differences in physiologic tolerance and provides a timely notification/warning such that personnel can take corrective action before missions are compromised or injuries are aggravated. HAMS will address cognitive and physiological workload at altitude and the dynamic impact of sustained high altitude operations. The effort under this program allows for iterative prototype development and testing to occur leading to an option for development of systems that are FDA cleared and ready for full field use.

3.0 Technical Progress

3.1 Task 1 – Initial Prototypes

3.1.1 Sensor(s) Definition

Preliminary evaluation has been completed for various sensing platforms of potentially increasing complexity but extended capabilities. Three medical development kits were evaluated; two from Texas Instruments and one from PhysioFlow. We are currently determining through design integration testing what OEM modules can be obtained and also leverage into a miniature design that could be used for the prototypes. We are also evaluating the cost of the projected final design versus the difficulty of incorporation and complexity as it relates to return on the investment of additional data outputs.

The first module evaluated in depth is from PhysioFlow which is a thoracic impedance system with exceptionally good motion tolerance. This system is a non-invasive hemodynamic monitor, providing cardiac output and other parameters by the use of standard impedance cardiography (SM-ICG) technique but the technology is more mature and stable than almost every other system we looked at. A unique feature of the system is a novel HD-Z filter for high motion/intense exercise tolerance noise cancellation. This system is also FDA cleared.

Additional parameters desired for the HAMS from this device may include:

- Stroke Volume/ Index
- Cardiac Output/Index
- Early Diastolic Filling Ratio (Preload Index)
- Systemic Vascular resistance (Afterload)
- Left cardiac ventricular Work Index
- Contractility Index
- Ventricular Ejection Time
- Ejection Fraction (est.)/ End Diastolic Volume (est.)

These parameters are more directly applicable to the CASEVAC mission of HAMS II. The PhysioFlow Q-Link product has USB communication and PC software to view and extract the data files and features include:



Figure 1. PhysioFlow Q-Link System

- Small Size: 126 x 96 x 20 mm
- Light Weight: Less than 200g
- 6 pre-gelled thoracic surface electrodes
- Advanced adaptive filter for noise cancellation (HD-Z™)
- Connections: Patient cable (1 meter), USB cable (1.8 meter) for data transmission and power supply (5V, 300 mA)
- Works with PhysioFlow® PF107 MS Windows™-based software for display, data analysis, and storage

- Minimum computer configuration:
 - Windows XP SP2 or later
 - Windows 7 (avoid Windows Vista) or later 1.7 GHz X86 processor
 - Ram : 1Go
 - Hard Drive 500 mo Free
 - 14 inch screen XVGA
- Recommended computer configuration:
 - Windows XP SP2 or later
 - Windows 7 (avoid Windows Vista) or later 2.3 GHz X86 processor
 - Ram : 2Go
 - Hard Drive 500 mo Free
 - 15 inch screen XVGA

Additional Technical specifications:

http://www.physioflow.com/rsc/PhysioFlow_QLINK_2011.pdf

Measuring Cardiac Output in HAMS II

The physiological parameter of Cardiac Output (CO) is simply defined as the amount of blood pumped by the heart in liters per min. CO is a hemodynamic parameter that plays a key role in several physiological equilibriums. Very unfortunately CO has so far been underused because of the invasive, cumbersome and inaccurate nature of the available measurement techniques. Their cost has also been a limiting factor.” (PhysioFlow, 2014)

CO is a more direct measure of cardiac performance than blood pressure, especially in shock or progressive hypovolemia. For instance: CO is essentially derived from the dynamic force of left ventricular contraction that generates arterial blood pressure by combination with the systemic vascular resistance (SVR) which limits the flow. Another example is the close interaction between CO, oxygen consumption (VO₂) and peripheral oxygen extraction described by the "Fick" equation in standard physiology. The mechanical efficiency of the heart or the amount of work divided by the amount of total energy exchanged is low at rest (about 10%), increasing dramatically in stress due to exercise and hypoxic response. In this case CO is the stroke volume of the heart times the heart rate and oxygen uptake is the cardiac output times the a-v difference. Similarly, relying on VO₂ only to evaluate the physiology of exercise in HAMS II is way too restrictive considering the importance of cardiac and peripheral parameters as potential limiting factors for human performance.

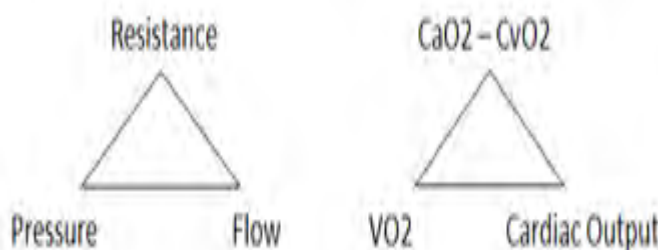


Figure 2. Pressure - Resistance - Flow Relationships

CO, Stroke Volume (SV) and their components (preload, contractility, after load) need to be evaluated in dynamic manner at least early in HAMS II testing to validate the measures in progressive hypoxia. Our plan is to include these measures non-invasively as part of the sensor package. For instance, the rate of increase of SV and contractility during exercise differs considerably from a heart failure patient to an athlete. As the US Navy SEALs work toward the elite athlete warrior program demographic it is reasonable to expect to see continued differences in not only baseline cardiac performance measures but also rates of change or shifts during stress. Likely these shifts are apparent in the subject demographics in HAMS II as well. Abnormal trend patterns in SV during exercise are proven signs of cardiac function impairment (e.g. coronary artery disease). Likewise, we might conclude these trends in a more standard military population are also indicative of capacity to perform in either or both a CASEVAC or ground operations application. Another example from critical care is fluid management. In CASEVAC, fluids are of paramount importance but as a balanced therapy to maintain pressure but prevent hypothermia and coagulopathy. Finally, we know that the evolution and variation of Stroke

Volume are markers of fluid status and need which may be directly a component of HAMS that would relate to the CASEVAC platform needs and drive fluid therapies.

Further lab testing will be required.

HAMS II Custom Pulse Ox:

Preliminary evaluation has been completed for on the TMS320C5515 DSP Medical Development Kit (MDK) for Pulse Oximeter Implementation. This evaluation system provides the capability to leverage into the design and development of HAMS II monitoring. This design provides the analog front-end boards using the C5515 DSP evaluation module (EVM) main board and additional TI analog components for medical applications.

Unlike other Pulse Oximeter OEM modules, this new design will allow for more flexibility in sensor control and provide a wider range of measurements for lab testing. The basic block diagram layout is in Figure 3. It is too early in R&D at this time to scope the number of pulse ox systems needed or feasible.

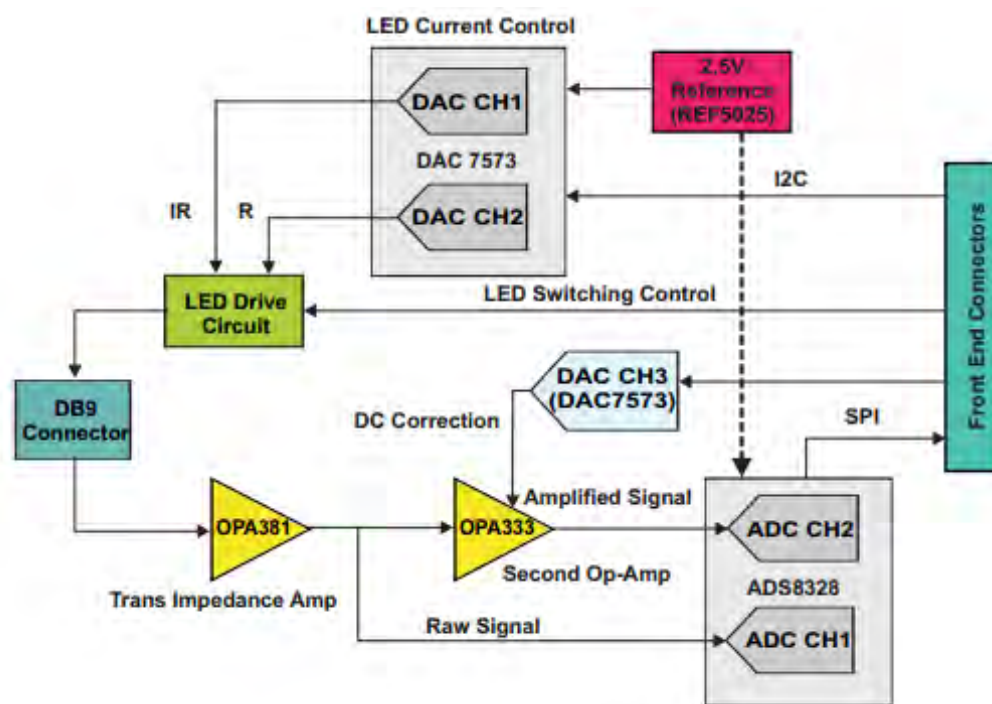


Figure 3. Pulse Oximeter Front-end Block Diagram

ECG Implementation on the TMS320C5515 DSP Medical Development Kit (MDK)

Preliminary evaluation has been completed for ECG Implementation on the TMS320C5515 DSP Medical Development Kit (MDK). This evaluation system provides the capability to leverage into the design and development of HAMS II monitoring. The major part of the design that can be integrated into HAMS II is the ADS1258. This chip allows the design to multiple channels of an ECG circuit process and limits the use of many differential amplifiers. Each channel is selectable for 3, 5 and 12 lead in software and disables any unused channel. The basic block diagram layout is in Figure 4.

The front-end board contains the following stages:

- Defibrillator protection
- Right leg driving circuit
- Lead off detection
- Derives eight ECG leads using differential amplifier (instrumentation amplifier)
- Low-pass filtering (anti-aliasing)
- Analog-to-digital conversion (ADC)

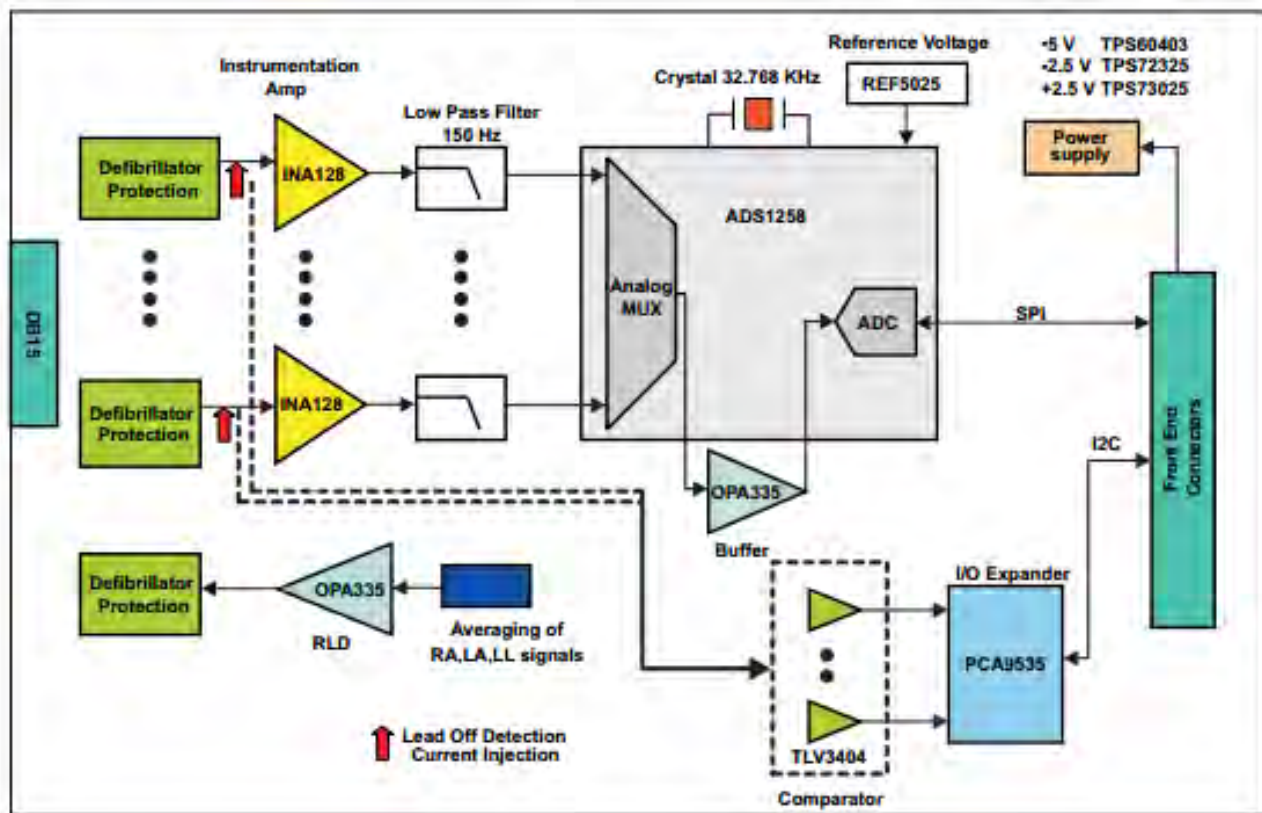


Figure 4. ECG Front-end Block Diagram

Leveraging from this design we started initial schematic layout seen in Figure 5, as a potential add on for the prototype system. Below is the 12 Lead ECG chip preliminary schematic. The ADS1298 24 bit ADC allowing for the signal to be less amplified and collected at a higher resolution for improved signal sampling and filtering. Leakage current and defibrillation protection. Protection is not part of the TI design but leveraged from previous R&D projects and FDA approved WVSM. This chip is user selectable, low power and improves the overall circuit size of the layout.

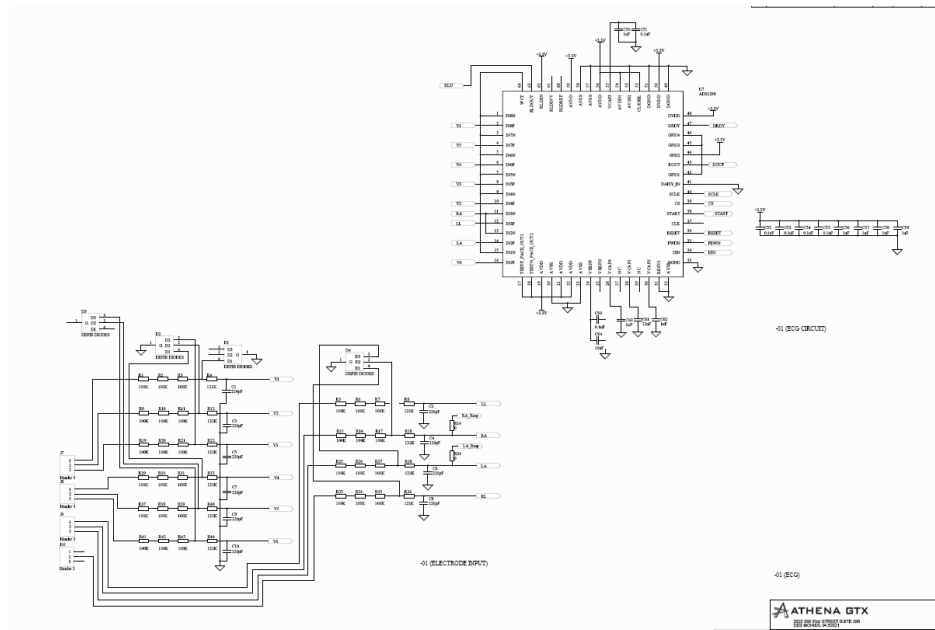


Figure 5. Initial 12 Lead ECG Schematic layout

It is proposed and now implemented that the Athena team is able to fast prototype the HAMS II options early because of technology leveraging from other related programs. The block diagram of the HAMSII system is compiled from leveraging other projects.

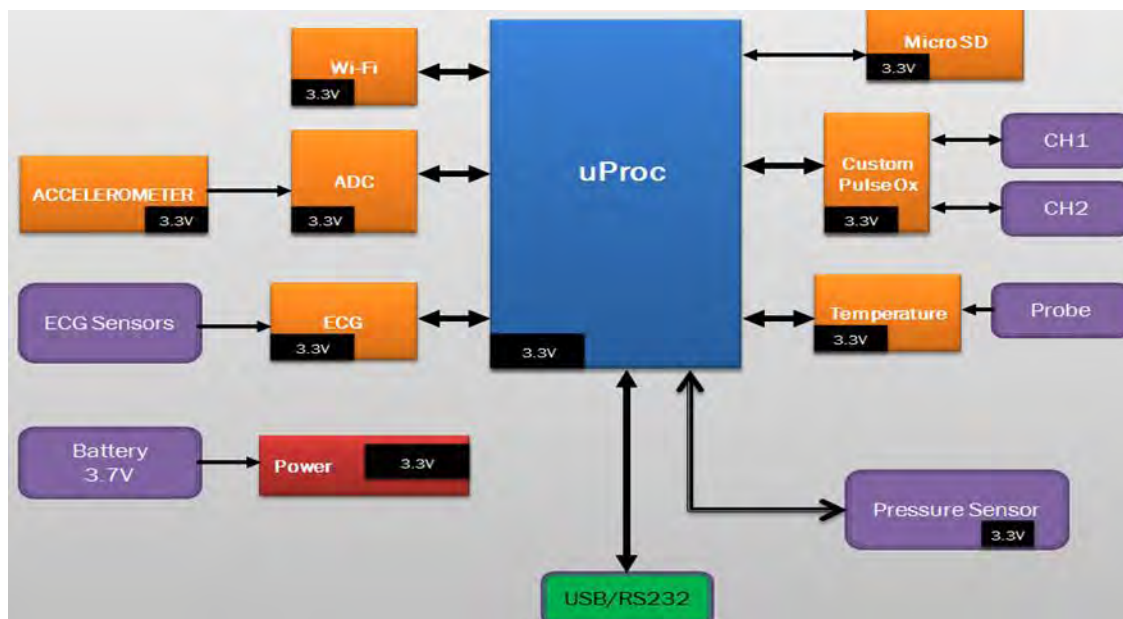


Figure 6. HAMS II Preliminary System Concept Block Diagram

The initial block diagram of the HAMSII system in Figure 6 uses concepts, and functional designs from previous Athena R&D projects. This will use development board review and custom design for providing various system capabilities. The system can be designed to transmit wirelessly, store the data in a micro SD card, or be USB/RS232 tethered.

Dual pulse Ox sensors adding redundancy with a custom design allowing plethysmography signals to be reviewed and pulse ox values to be collected even at lower levels. The temperature module will provide core temperature using an ear type sensor with an option to have a thermistor used in other parts of the body including temporal skin temperature or body core (tympanic membrane, armpit, or rectal). The pressure sensor would be used for altitude detection. A 3 axis accelerometer for subject orientation and data filtering improvements can be integrated. Potential for pressure sensing for blast overpressure is a key consideration.

Further definition and development of this design will be with the collaboration of the team and results from various development board tests.

Microprocessor Selection

Investigation into applicable microprocessors and associated development boards was completed. The K70 Series processor from Freescale is our primary target environment. Further testing and design development was done on the custom pulse-ox.

3.1.2 Enclosure Concept Definition

Starting from the Hammerhead baseline configuration, updated enclosure concepts are being developed. Removal of the underwater capabilities will give the design more flexibility and should reduce size and bulk. Initial enclosure concepts have been started.

3.1.3 Electronics Board Schematic and Layout

This task has not been started.

3.1.4 Software Functions and Design

As the specific hardware and microcontroller are identified we will continue to develop a draft of the Software Requirements Specification (SRS) from the draft Functional Requirements Specification (FRS). This will drive the draft Software Design Description (SDD) that defines the software architecture and interfaces to hardware. These are living documents in the early phases of concept exploration and initial prototyping so we can capture the design as it is evolving and better prepare for the next steps.

3.1.5 Algorithm(s) Incorporation

Both algorithms developed under Phase I of HAMS remain viable for use in HAMS II. We have begun the process of determining the best way to use these as we move forward. There are several paths forward:

- Each model can act independently with a decision fusion for a final outcome,
- One can focus on prediction of parameters and one can predict state,
- One model can feed the other data during periods of sensor dropouts or
- Combinations of the above depending on the data availability.

The top level block diagram from Phase I is included below.

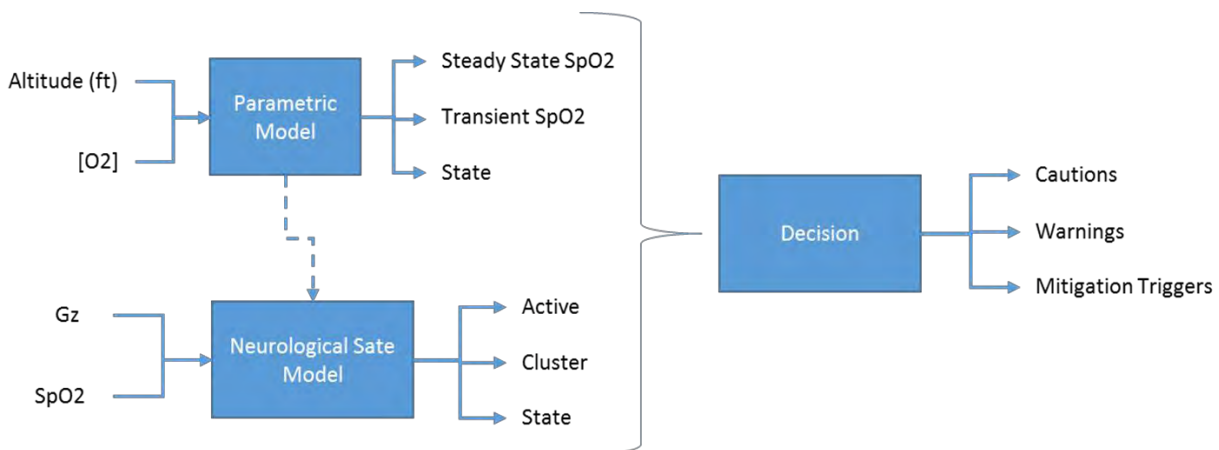


Figure 7. Top Level Model Block Diagram

The specific hardware (microcontroller) design and associated memory implementation are required to fully realize the detailed design. Our initial thoughts are to develop two modes of operation:

- Minimal data (Altitude and Gz only)
- All data from Sensors (Altitude, [O2], Gz, SpO2)

Additional altitude data was uploaded to the FTP site by Dr. Shender in late November. Initial analysis of the data was performed. A summary and detailed analysis are include below. Additional model run outputs are included in the Appendix – Section 9 of this report.

Data Analysis and Model Prediction Summary

Both NIRS and Pulse-Ox data were evaluated at exposures of 10,000 feet, 18,000 feet and 25,000 feet.

- NIRS – Exposure to altitude produced expected reduction in regional oxygen levels. There was a return to near baseline (pre-exposure) after the 10,000 foot test exposure, however, the higher test exposure levels (18K and 25K feet) did fall short of pre-exposure sea level values.
- Pulse-ox – Exposure to altitude produced expected reduction in oxygen levels. The dynamic range of the Pulse-Ox is greater than the NIRS signal.

Neurological Model Predictions using the pulse-ox data were performed. For the 18,000 feet case there was one predicted LOC while the remainder were considered impaired. For the 25,000 feet case the model predicted on “OK” case which is due to a very short exposure with 57% impaired and 29% LOC. Dropping the one subject it raises the impaired to 67% and the LOC to 33%. In reviewing the spreadsheets it is not apparent that any subject lost consciousness and since oxygen application criteria were in place to avoid this condition the likelihood of LOC happening would be remote. The next step in the process is to evaluate the SYNWIN data against the predictions but a cursory look at the composite scores data was not compelling so a more in-depth evaluation may be indicated.

Detailed Analysis and Model Predictions

Two aspects of the data were examined. First the use of a newer version Near Infra-red Spectroscopy system was reported for relative regional cerebral tissue oxygenation and these results were specifically examined for signal robustness in the anticipated use case. The altitude run Pulse Oximetry data was also run through the neurological state predictor to compare predicted and experimental results.

Brief Description of Altitude Chamber Study – A more comprehensive description of the US Navy study can be found in the protocol (NAWCAD.2013.0008-CR01) uploaded to the project site. Subjects were exposed to altitudes of 18,000 and 25,000 feet for two separate exposures giving at most four data sets for analysis. The table below is reproduced from the protocol to give the procedure and process which the data response reflect where MH is moderate hypoxia and SH is severe hypoxia.

Table 1. Altitude Chamber Protocol Summary

	Altitude (ft)	Ambient O ₂ partial pressure (mmHg)	Alveolar O ₂ partial pressure (mmHg)	Description	%O ₂ in breathing air supply
MH	0	159.2	103.0	15 min at Ground Level (GL)	21%
				120s ascent to 10,000 ft at 5,000 fpm	21%
	10,000	109.5	61.2	10 min at 10,000 ft	21%
				Pre-breathe 100% O ₂ for 30 minutes, switch to air (21% O ₂) followed by 96s ascent to 18,000 at 5,000 fpm	100% / 21%
	18,000	79.6	37.8	Up to 20 min at 18,000 ft	21%
				216s descent* to GL at 5,000 fpm	21%
	0	159.2	103.0	15 min at GL	21%
SH	0	159.2	103.0	15 min at Ground Level (GL)	21%
				120s ascent to 10,000 ft at 5,000 fpm	21%
	10,000	109.5	61.2	10 min at 10,000 ft	21%
				Pre-breathe 100% O ₂ for 30 minutes, switch to air (21% O ₂) followed by 180s ascent to 25,000 at 5,000 fpm	100% / 21%
	25,000	59.2	30.4	Up to 20 min at 25,000 ft	21%
				300s descent* to GL at 5,000 fpm	21%
	0	159.2	103.0	15 min at GL	21%

The exposure was terminated if the SpO₂ at finger fell below 60% for more than 10 seconds, the subject stopped responding to the multitask for more than 10 seconds, the exhaled end tidal oxygen pressure as measured by a Gas Chromatograph Mass Spectrometer fell below 30 mmHg. If the termination threshold was exceeded, 100% oxygen was provided and the chamber brought back down to ground level. The referenced multitask used was the SYNWIN task battery which data was collected except during the pre-breathe and descent periods. At present the results for four subjects was placed on the project site. The present state of assessment is discussed below. Full sized graphs are included in the appendix.

NIRS Results

For the 18,000 feet exposure the table of graphs below shows the NIRS results for both exposures and the altitude profiles. Subject 4 had only one exposure and the altitude data was not included. Clearly the NIRS responds to both the 10,000 feet and 18,000 feet levels with return to a “baseline” is noted. For Subject 2 (upper right hand) first exposure the baseline does not return to near pre-exposure levels.

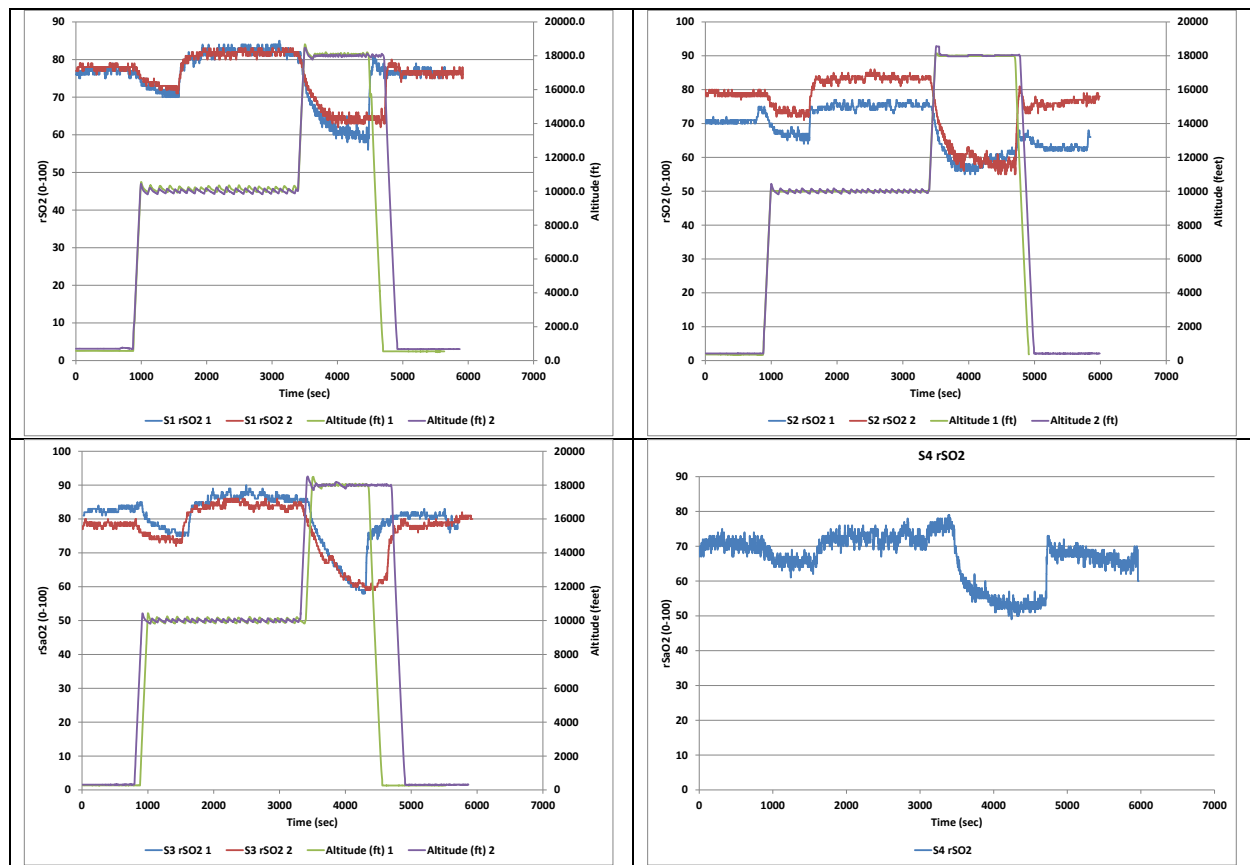


Figure 8. 18,000 feet exposure NIRS results

For the 25,000 feet exposure, the table of graphs below shows the NIRS response along with the altitude level. The NIRS system used was responsive at the 10,000 feet level. The exposure durations at 25,000 feet are shorter given the severity of the exposure and the NIRS response does not have time to reach an asymptote for some cases which means some other indicator may have triggered a run termination.

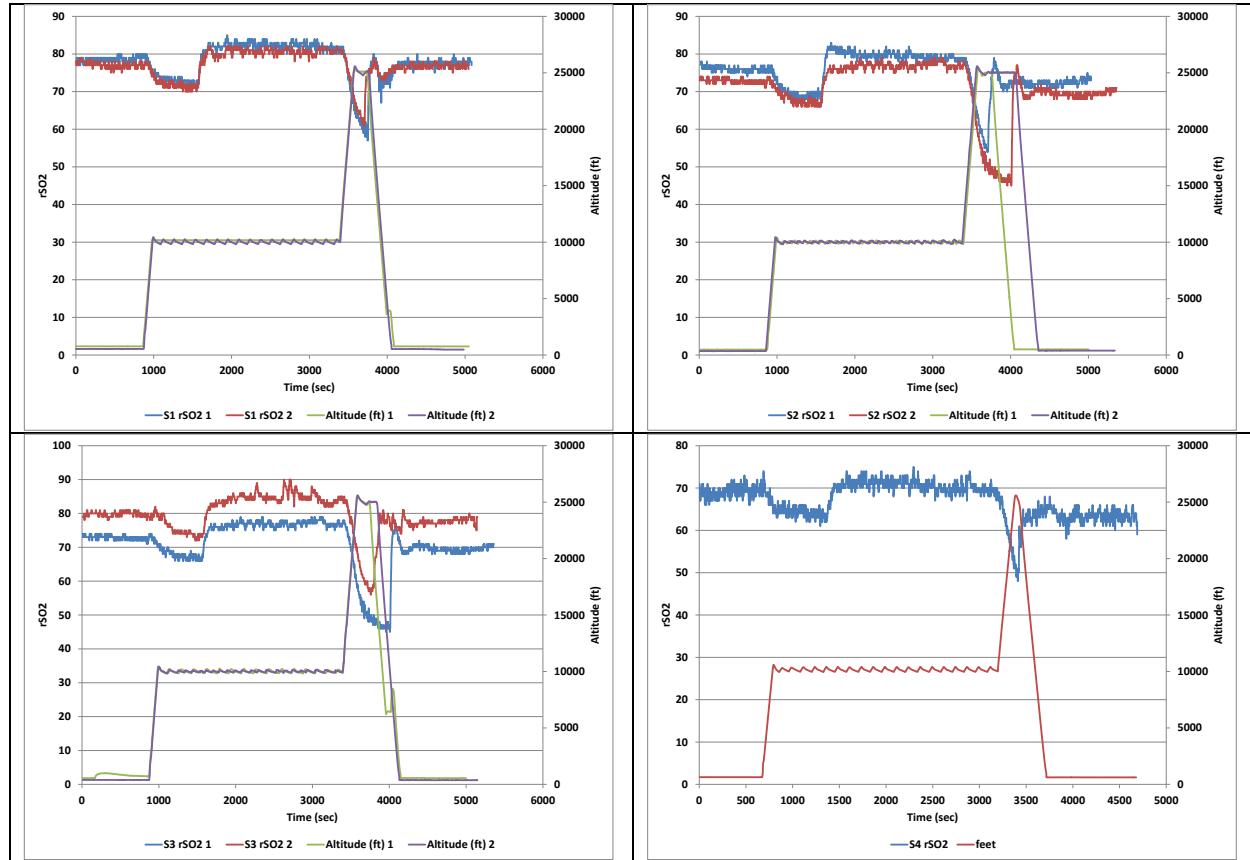


Figure 9. 25,000 feet exposure NIRS results

As with the 10,000 feet exposure a return to a baseline is seen but in both exposure cases the post-altitude baseline appears lower than the initial non-stressed period. This is interesting considering the 100% oxygen pre-breathe period may have created some minimal cerebral oxygen storage which is no longer seen after the stressor and decent under 21% oxygen. But generally the post exposure baseline is lower than the sea level baseline by a few points.

Pulse Oximeter versus NIRS at 25,000 feet

The Pulse Oximeter signal was compared to the NIRS signal at the 25,000 feet exposure. The Pulse Oximeter requires pulse detection while the NIRS does not. The table of figures below shows the comparison between the two signals for each subject and exposure. While comparable responsiveness is noted in time history of the exposure events, the dynamic range for the significant event (25,000 feet) appears larger for the Pulse Oximeter which starts at “100” versus “80” – “70” for the NIRS and reaches relatively the same “low” value as the NIRS signal. For the lesser stressor, 10,000 feet, the relative change in signal appears comparable.

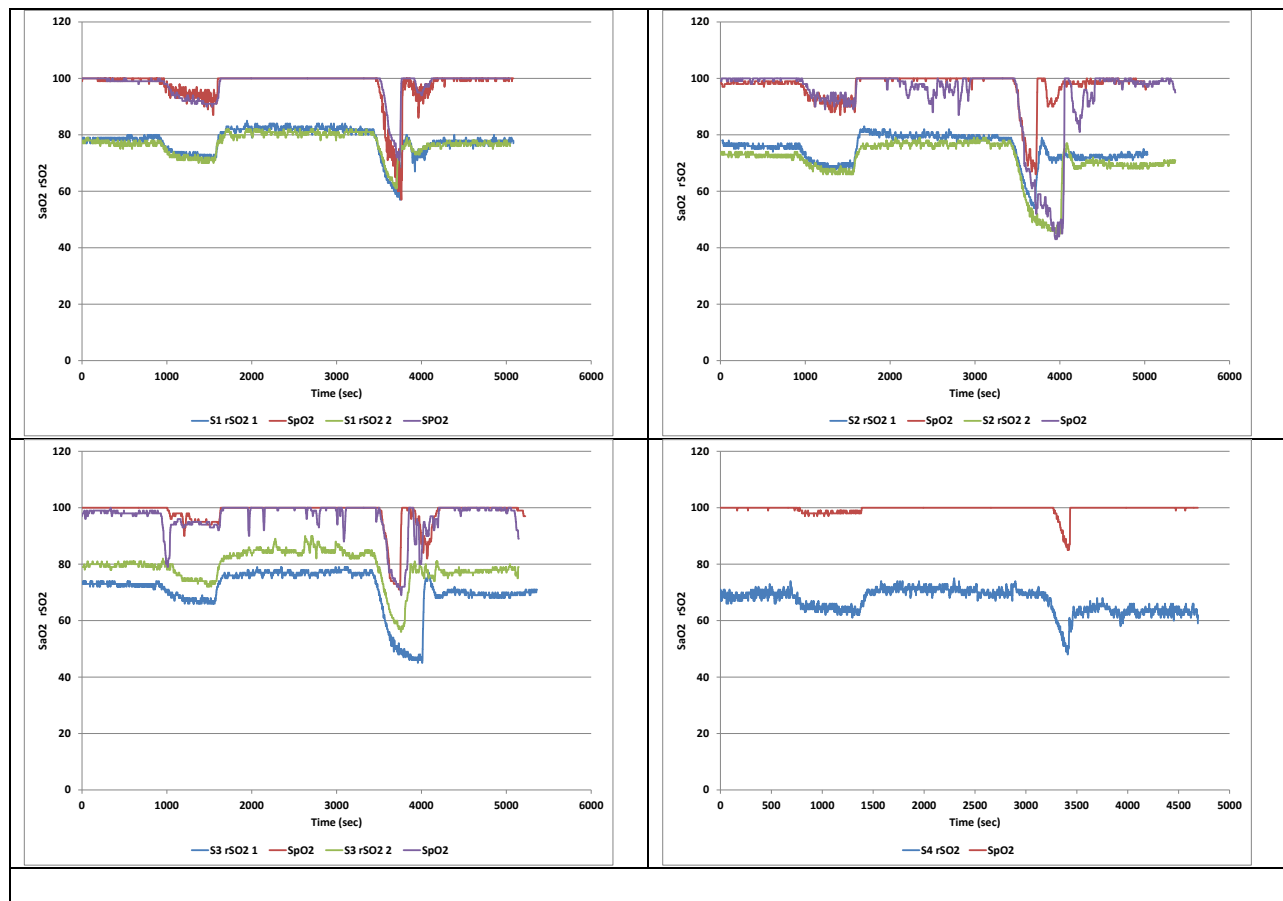


Figure 10. Pulse Oximeter versus NIRS

NIRS response with respect to altitude level

The average lowest NIRS value during the hypoxia exposure was plotted against altitude for each subject with the group average and one standard deviation shown in the graph below. The plot shows a biphasic nature with the breakpoint in slope occurring at 10,000 feet. This “breakpoint” is dictated by the available data and the exact point of the change in slope is not known with certainty. However a slope change at 10,000 feet may be considered as reasonable given what is currently known about altitude physiology. The corridor of response is given by the starting NIRS values representing “normal” sea level cerebral oxygenation and for the most part follow along the exposure trend when considering the lowest point value. Subject 1’s exposure at 25,000 feet was so short as to not give time to reach an asymptote and was not included to show that all the remaining subjects reached the same point at 25,000 feet which may represent a practical “floor” signal limit for the NIRS device.

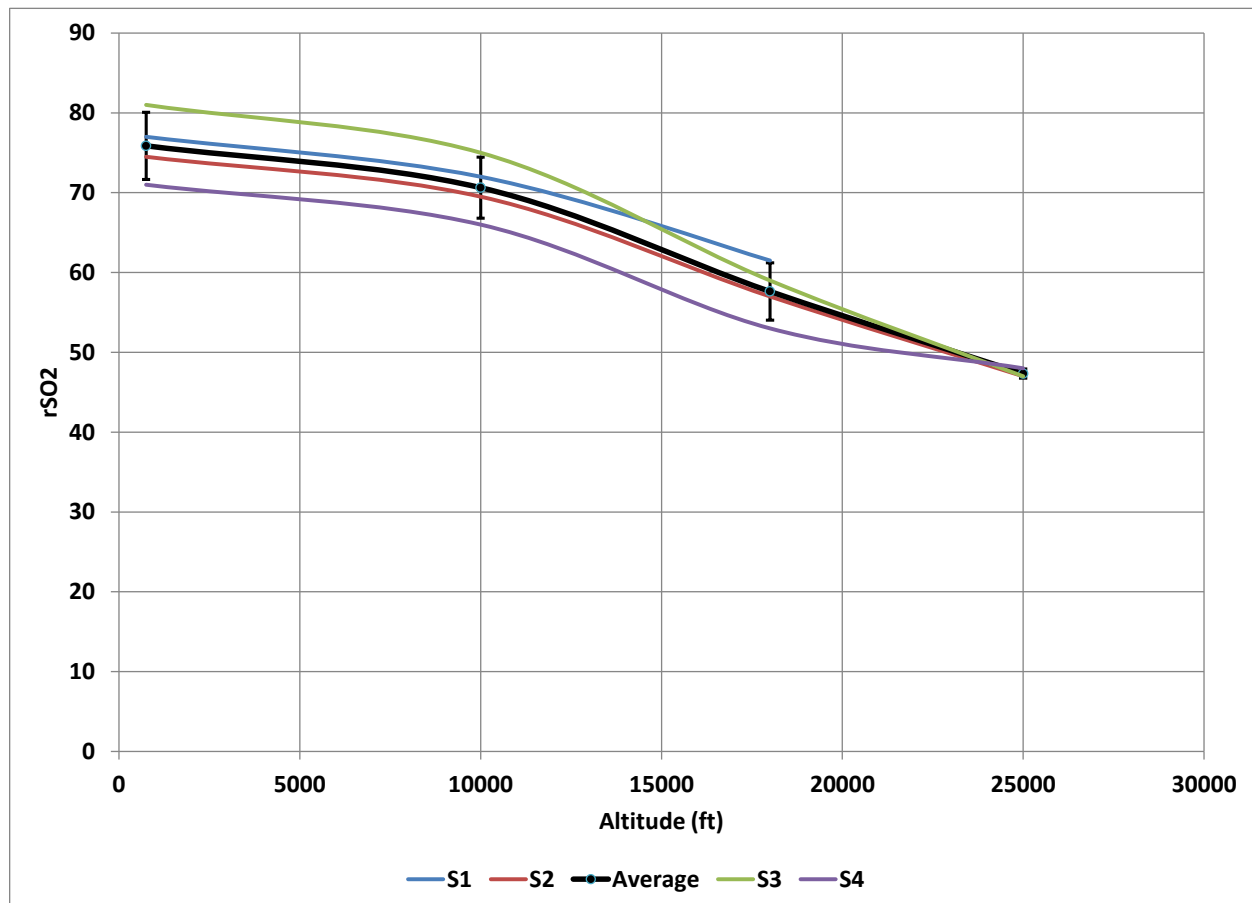


Figure 11. Average Lowest NIRS Value vs. Altitude

The 18,000 feet and 25,000 feet exposures fall below the stated manufacturer’s (Massimo) threshold of concern of “60” for the signal. However in the range of 10,000 to 15,000 feet, practical ground soldier

mission altitudes, the level is above that threshold and the average signal delta between 10,000 and 15,000 feet is approximately 13 units. The Pulse Oximeter data at 10,000 feet was typically 20 points higher but fell to close to the same low level which gives an approximate signal delta between 10,000 and 15,000 feet of probably 30 units.

While the two measurement sites may not be comparable, finger for Pulse Oximetry and forehead for NIRS, the dynamic range implications in terms of algorithmic state detection are important. The poor Pulse Oximetry data for Subject 3 and 4 above may be from location considerations. Both signals need to be examined in the ambulatory sense that they will be used for soldiers to determine the limitations in detection when the event is not known.

Neurological Model Predictions

The Pulse Oximetry data was ran through the Neurological State Predictor to determine the predicted state. The simulation screen shots are contained in the appendix and the table below summarizes the results.

Table 2. Neurological Model Prediction Results

		Lowest Neurological State		
Subject	Altitude	OK	Impaired	LOC
1	18,000		*	*
2			*/*	
3			*/*	
4			*	
Count		0	6	1
Percentage		0%	86%	14%
1	25,000		*	*
2			*	*
3			*/*	
4		*		
Count		1	4	2
Percentage		14%	57%	29%

LOC – loss of consciousness

For the 18,000 feet case there was one predicted LOC while the remainder were considered impaired. For the 25,000 feet case the model predicted on “OK” case which is due to a very short exposure with 57% impaired and 29% LOC. Dropping the one subject it raises the impaired to 67% and the LOC to 33%. In reviewing the spreadsheets it is not apparent that any subject lost consciousness and since oxygen application criteria were in place to avoid this condition the likelihood of LOC happening would be remote. The next step in the process is to evaluate the SYNWIN data against the predictions but a cursory look at the composite scores data was not compelling so a more in-depth evaluation may be indicated.

3.1.6 Initial User’s Manual

This task has not been started.

3.1.7 Fabricate Prototypes

This task has not been started.

3.1.8 Test Prototypes for Delivery

This task has not been started.

3.1.9 Deliver Initial Prototypes

This task has not been started.

3.1.10 Test & Evaluation Support

This task has not been started.

3.2 Task 2 – Design and Development Evolution

This task has not been started.

3.2.1 Design Definition

This task has not been started.

3.2.2 Preliminary Design 1

This task has not been started.

3.2.3 Preliminary Design 2

This task has not been started.

3.2.4 Fabricate Prototypes

This task has not been started.

3.2.5 Test Prototypes for Delivery

This task has not been started.

3.2.6 Deliver Preliminary Prototypes

This task has not been started.

3.2.7 Test & Evaluation Support

This task has not been started.

3.3 Task 3 (Option) – Production Ready HW/SW

This task has not been exercised.

3.4 Task 4 (Option) – Preliminary Human Testing of SpO2 Sensor and Electronics

This task has not been exercised. This task will be performed in conjunction with Task 2 development. It is included as an option because it requires human testing.

3.5 Task 5 (Option) – Final Human Testing of SpO2 Sensor and Electronics

This task has not been exercised. This task will be performed in conjunction with Task 3 development. It is included as an option because it requires human testing.

4.0 Financial Progress

The total base budget for the HAMS program is \$1,985K plus an Option 1 of \$905K, Option 2 of \$49K and Option 3 of \$47K. The contractually obligated amount in FY2014 towards the total budget is \$298K. The contractually obligated amount in FY2015 towards the total budget is \$305K. Costs incurred to date through this performance period are \$215K or approximately 72% of FY14 obligated funding. No FY15 funds have been incurred.

The tables below summarize the costs incurred to date against the FY 2014 and FY 2015 obligated funding to date (\$298K and \$305K, respectively). A more detailed spread sheet has been included in the Appendix, Section 9.1.

4.1 FY2014 Funding (\$298K)

Month	HAMS Projected (%)	ONR Benchmarks FY14 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
SEP-OCT	25	58	34	-24	
NOV	50	63	54	-9	
DEC	75	68	72	+4	Additional funding received on DEC 12, 2015.
JAN	100	73			

4.2 Benchmarks for FY2015 Funding (\$305K)

Month	HAMS Projected (%)	ONR Benchmarks FY15 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
JAN		6			
FEB		12			
MAR		20			
APR		23			
MAY		29			
JUN		35			
JUL		42			



5.0 Schedule and Deliverables

5.1 Schedule



[illegible]

Progress/Completed
Planned

[illegible]

Tasks / Milestones	FY 2017											
	CY 2016			CY 2017								
	O	N	D	J	F	M	A	M	J	J	A	S
2. Design and Development Evolution												
3. (Option) Production Ready HW/SW												
5. Human Testing SpO2 sensor (Option)												
Milestones / Deliverables												
Monthly Updates												
Quarterly Reports												
Final CDR												
Formal Test Devices (5) Complete												
Verification Design Review												

Tasks / Milestones	FY 2018											
	CY 2017			CY 2018								
	O	N	D	J	F	M	A	M	J	J	A	S
3. (Option) Production Ready HW/SW												
Milestones / Deliverables												
Monthly Updates												
Quarterly Reports												
FDA 510(k) Submission												
Validation Design Transfer Review												
FDA Clearance Determination												
Final Design Review												
Deliver Final Test Units												

 Progress/Completed
 Planned

5.2 Deliverables

5.2.1 Monthly Updates

The following monthly reports have been submitted to ONR for this reporting period:

- A003-01/02 HAMS II Monthly Update – OCT/NOV 2014
- A003-03 HAMS II Monthly Update – DEC 2014

5.2.2 Quarterly Reports

The following quarterly reports have been submitted to ONR for this reporting period:

- A001-1, Report for the period September 30, 2014 to December 31, 2014

5.2.3 Final Report

- A002 Not due until August 2016.

5.2.4 Initial Prototypes

- A004 Not due until August 2015.

5.2.5 Preliminary Prototypes

- A005 Not due until August 2016.

6.0 Conclusion

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report. Work has been started on Task 1. . Optional Tasks 3, 4 and 5 have not been exercised.

Initial work has been concentrated on finding advanced sensors to assist in laboratory investigation for verification/validation work and potential use in the CASEVAC applications. Also a custom pulse-ox has been pursued to optimize the sensor and electronics for the upper arm location. An initial system block diagram has been created as well as selection of a target microprocessor. Capabilities for the system include: WiFi, Accelerometer, ECG, Pressure (altitude), Temperature, Pulse-ox, micro-SD and USB. Enclosure design concepts have been started and will initially be leveraged from work done on Hammerhead as a baseline.

Both algorithms developed under Phase I of HAMS (Parametric and Unconsciousness Models) remain viable for use in HAMS II. We have begun the process of determining the best way to use these as we move forward. The Unconsciousness Model has morphed into more of a Neurological State Model. An analysis of NIRS and SpO2 data provided by Dr. Shender from an altitude chamber study was completed. This included running the Neurological State Model predictions using the SpO2 data with promising results for higher altitudes (18,000 and 25,000 feet). The NIRS data produced expected in regional oxygen levels as did the SpO2 data. The SpO2 data produced a wider dynamic range. NIRS still seems to suffer from a return to pre-exposure baseline.

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

7.0 Recommendations

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract. We are encouraged that the ONR continues to pursue the remaining funding in a timely manner to keep the team together.

8.0 References

Not Applicable.



9.0 Appendix

9.1 Detailed Financial Spreadsheets (PDF)

N00014-14-C-0276 - OVERALL SPENDING

		OCT 2014 MO-1	NOV 2014 MO-2	DEC 2014 MO-3
Base Contract Award	1,985,403.00	100,199.76	61,234.13	53,650.29
	Expended % by Month	5.0%	8.1%	10.8%
	Cumulative Spending	100,199.76	161,433.89	215,084.19

FUNDING 2014	298,679.00	100,200.00	61,234.00	53,650.00
	2014 Benchmark	57.87%	63.12%	67.67%
	2014 FY Expenditure Rate	33.55%	54.05%	72.01%
	Invoice #	1165, 1168, 1170	1176, 1178,	1181, 1185



HAMS-2 FY 2014 - ACRN 000101-AA/000102-AB						
CONTRACT# N00014-14-C-0276						
Begins Sept 25, 2014 - Jan 31, 2015	4+ months	ACTUAL EXPENDITURE % BY MONTH based on 298K				
				33.55%	54.05%	72.01%
HAMS 2 FY 2014	CUMULATIVE SPENT FY14 FUNDS	REMAINING BUDGET	% of Total FUNDS Expended	MO 1 - SEP-OCT 2014	MO 2 - NOV 2014	MO 3 - DEC 2014
COST INCURRED	\$ 215,084	\$ 83,594	72%	\$ 100,199.76	\$ 61,234.13	\$ 53,650.29

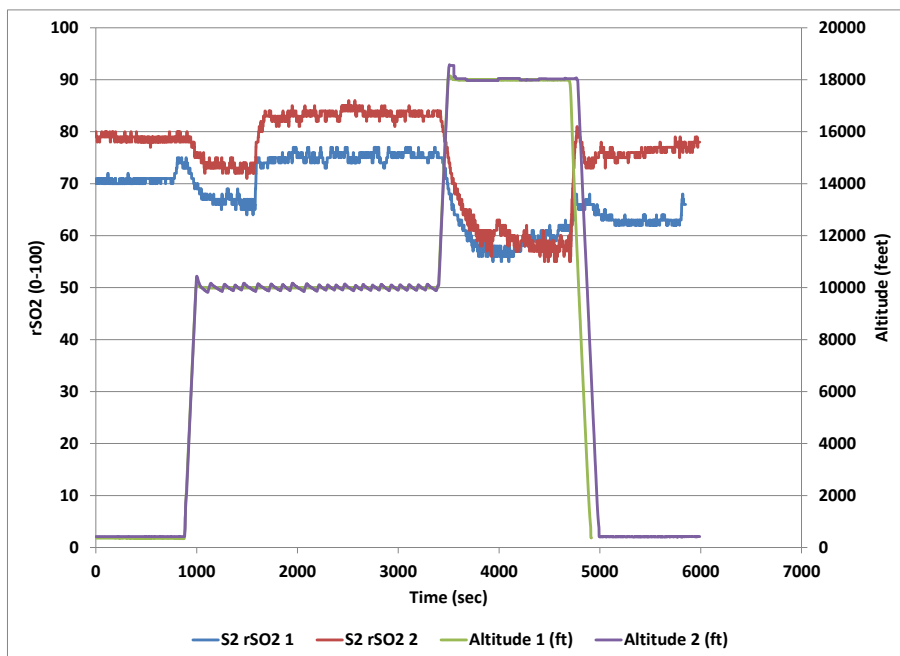
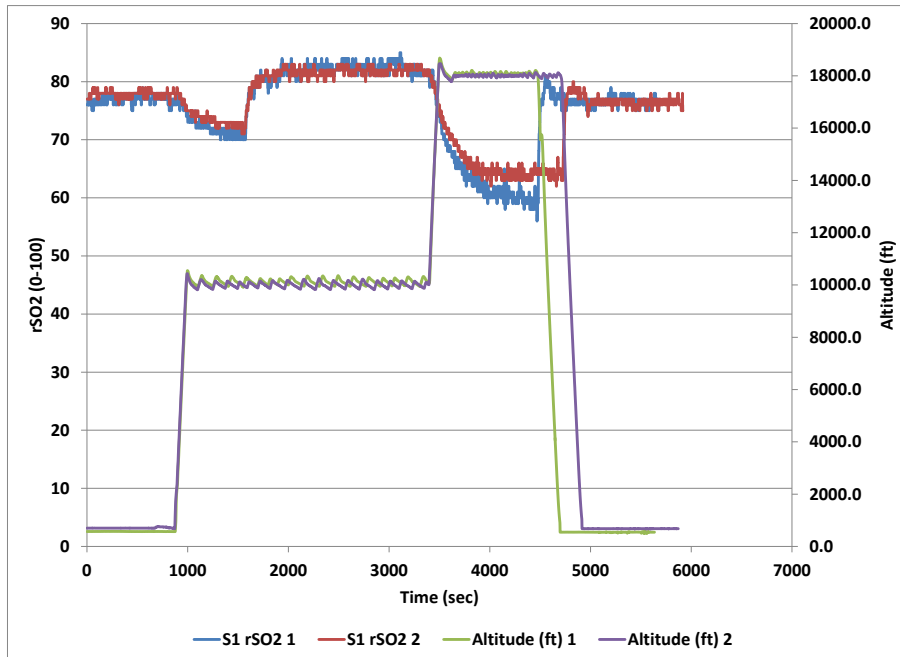
HAMS 2 FY 2014	BUDGET #1	MO 1 - SEP-OCT	MO 2 - NOV	MO 3 - DEC
BUDGET ACRN 000101-AA	\$ 298,679	\$ 73,633.85	\$ 75,254.92	\$ 73,771.70
Projected expenditure % based on 298K budget		24.65%	49.85%	74.55%
Benchmark FY14		57.87%	63%	67.67%

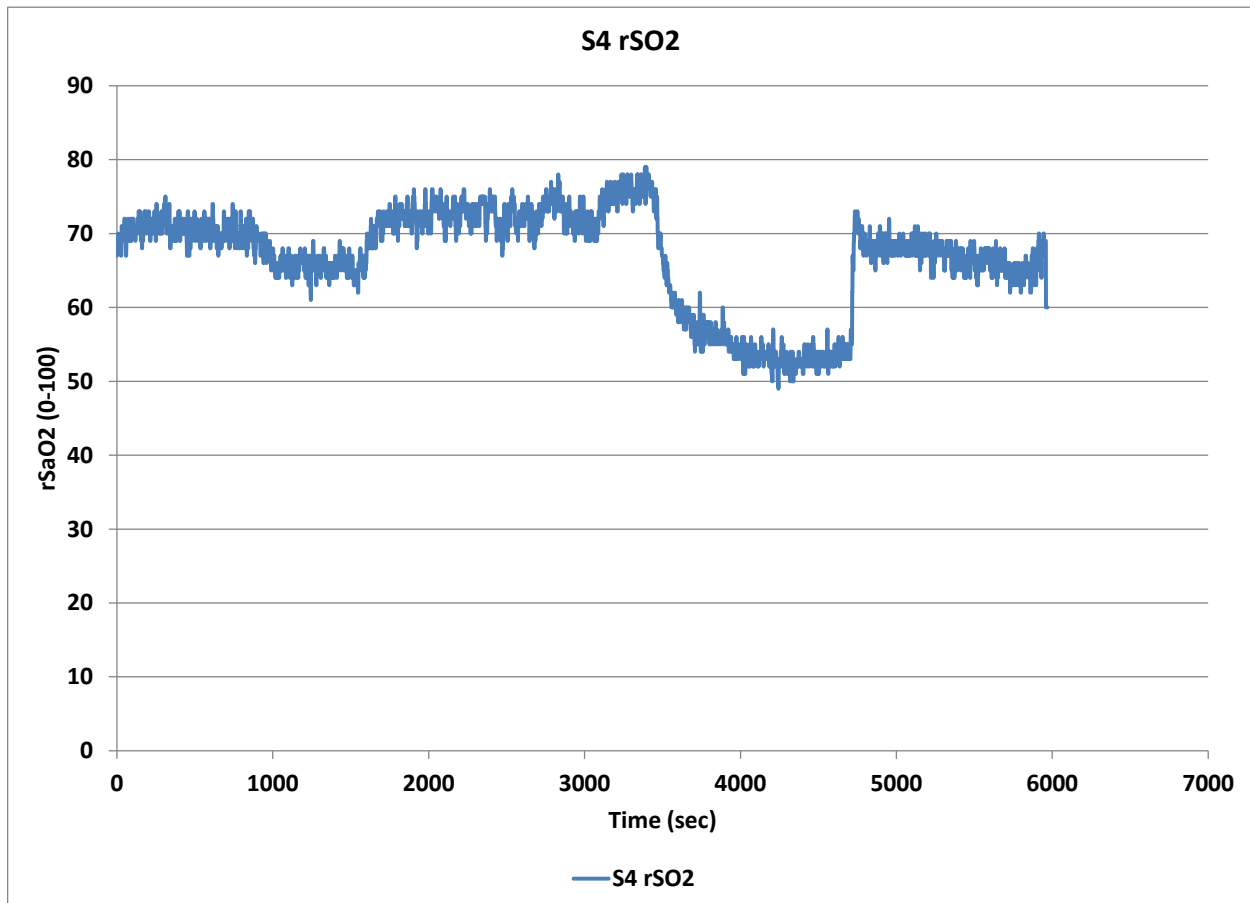
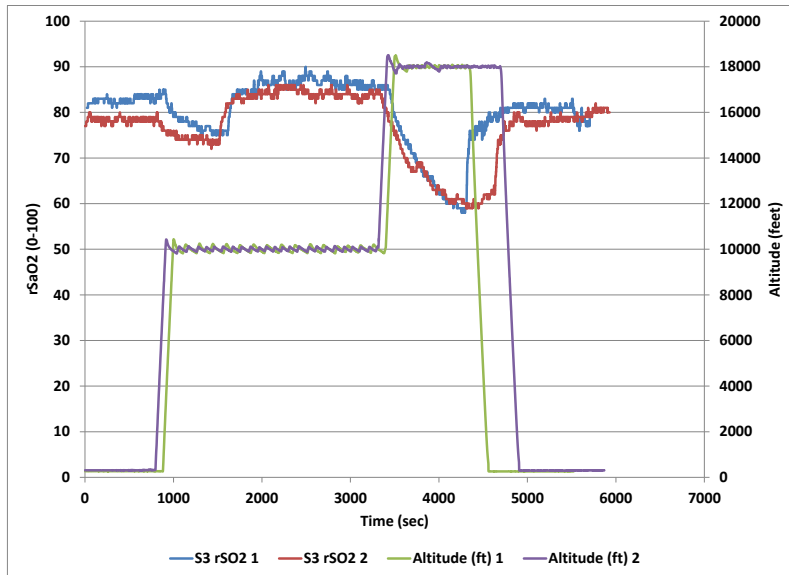


9.2 NIRS, Pulse-Ox and Model Outputs

NIRS Results

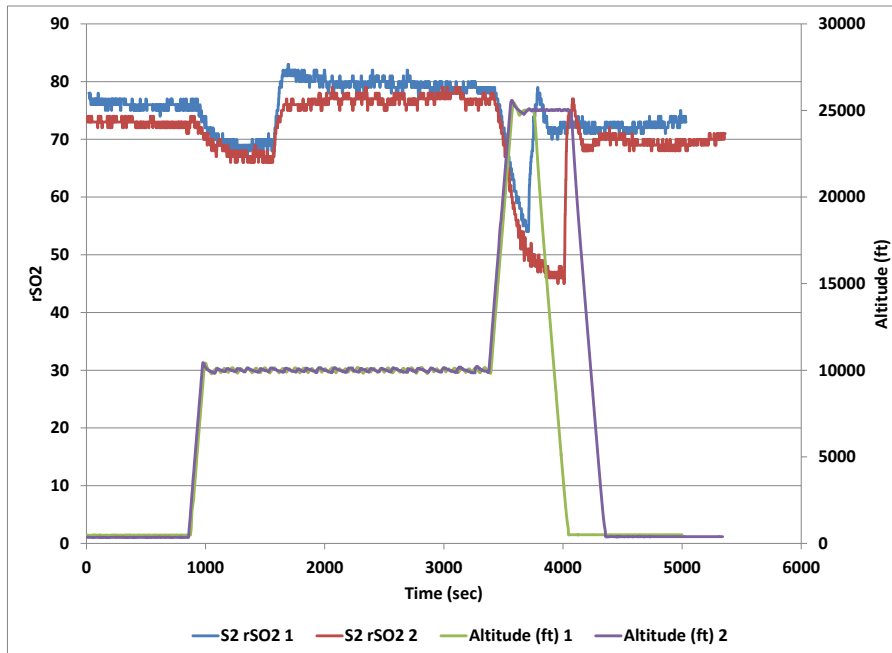
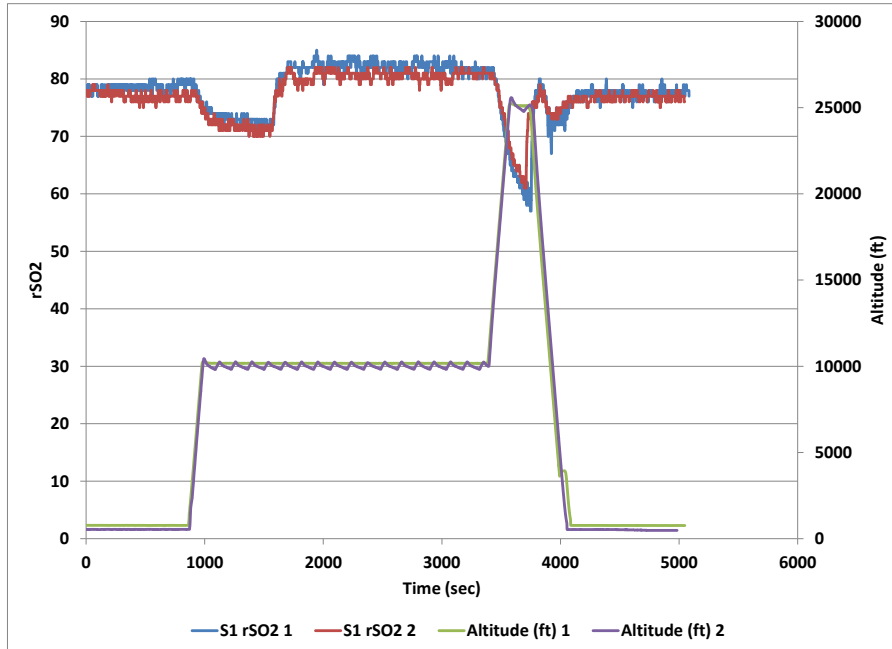
18,000 Feet

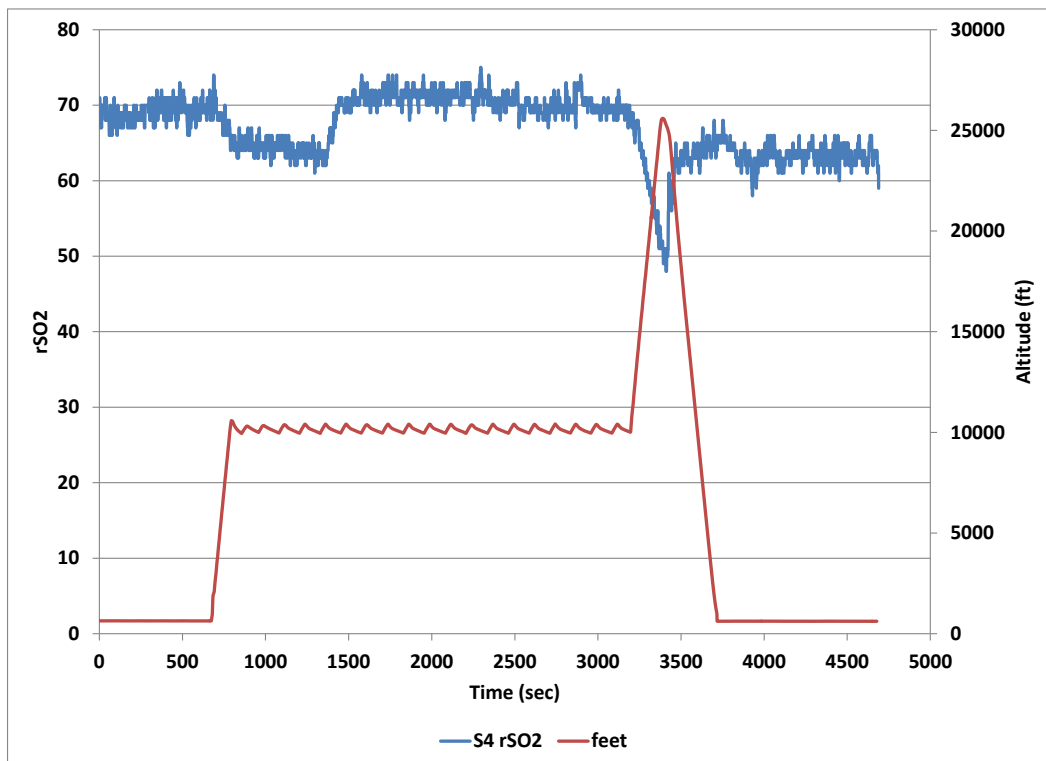
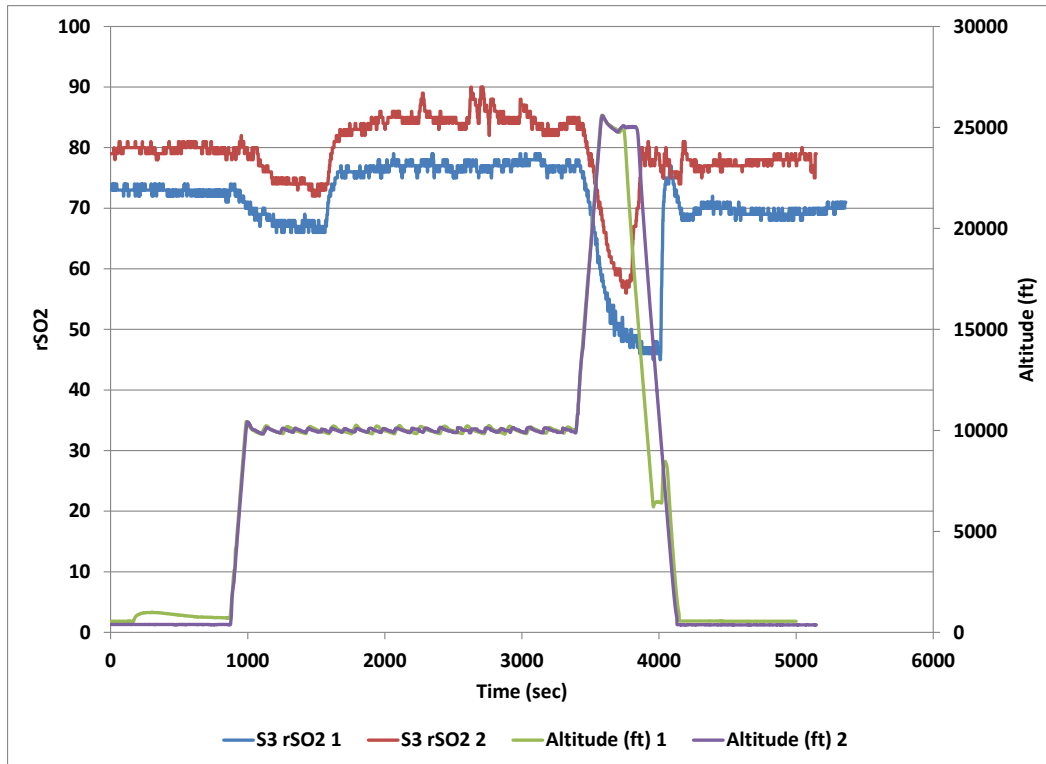






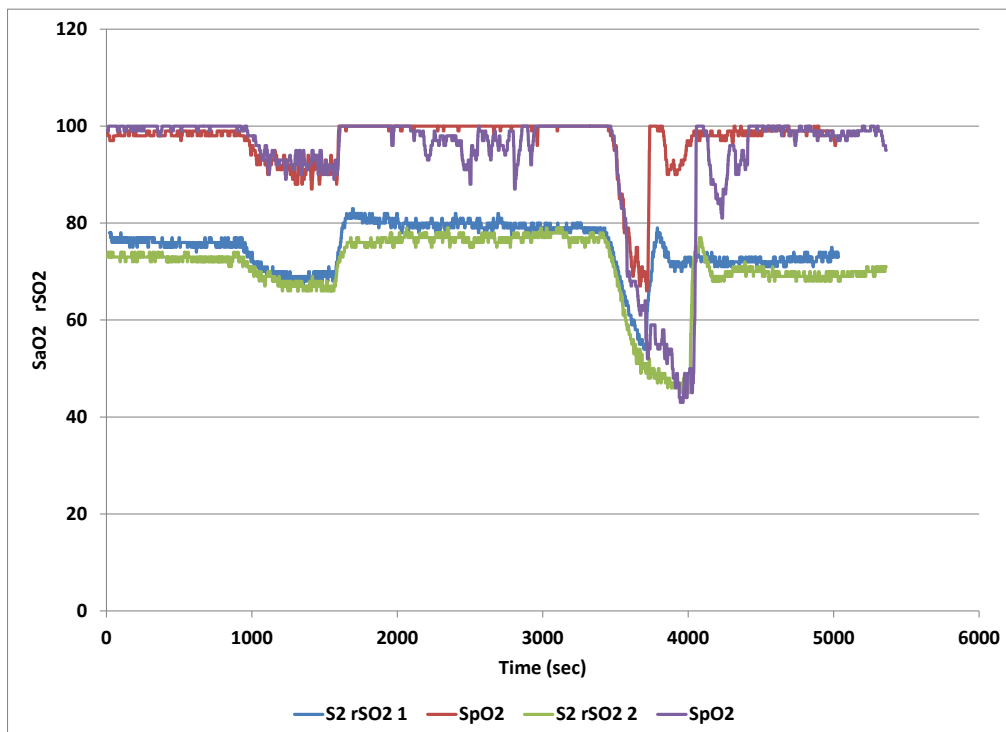
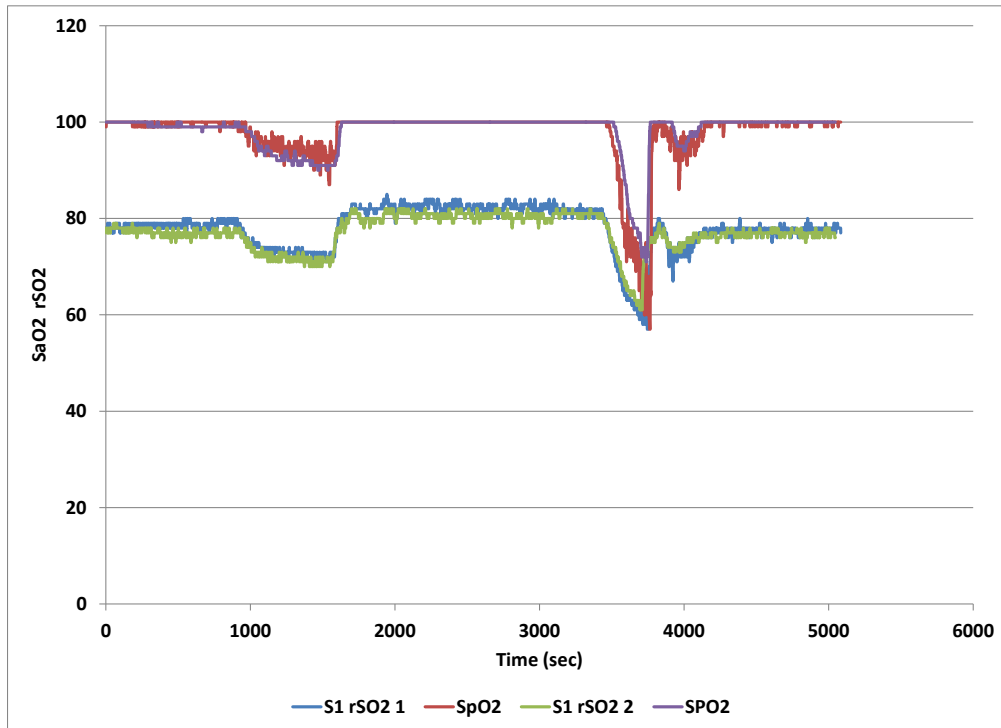
25,000 Feet

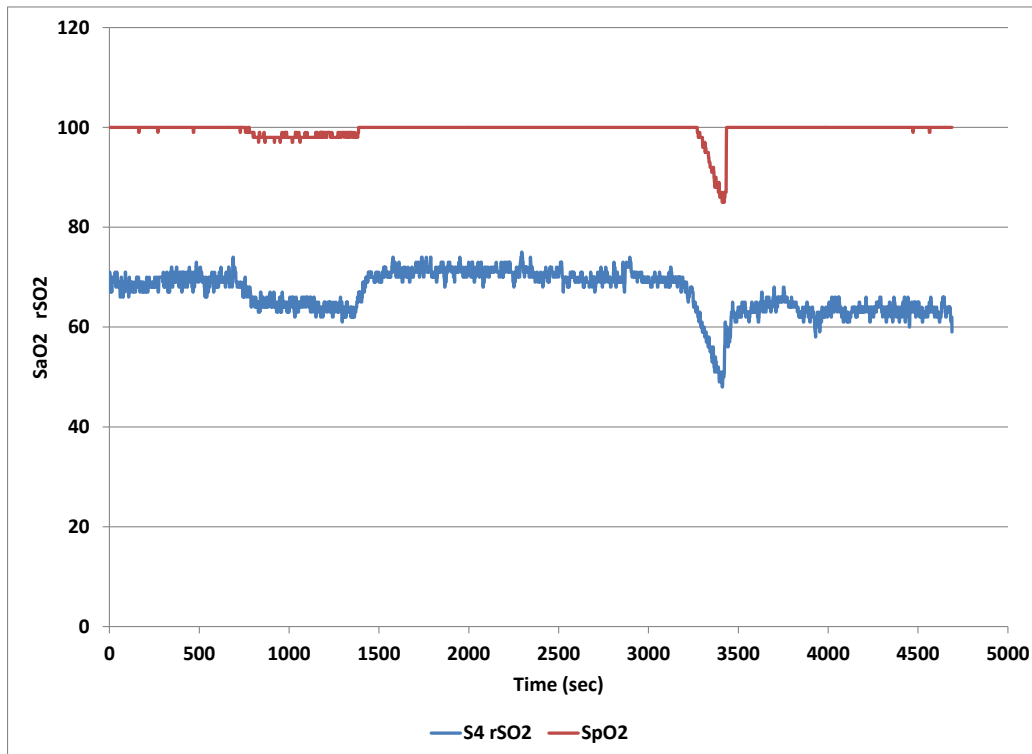
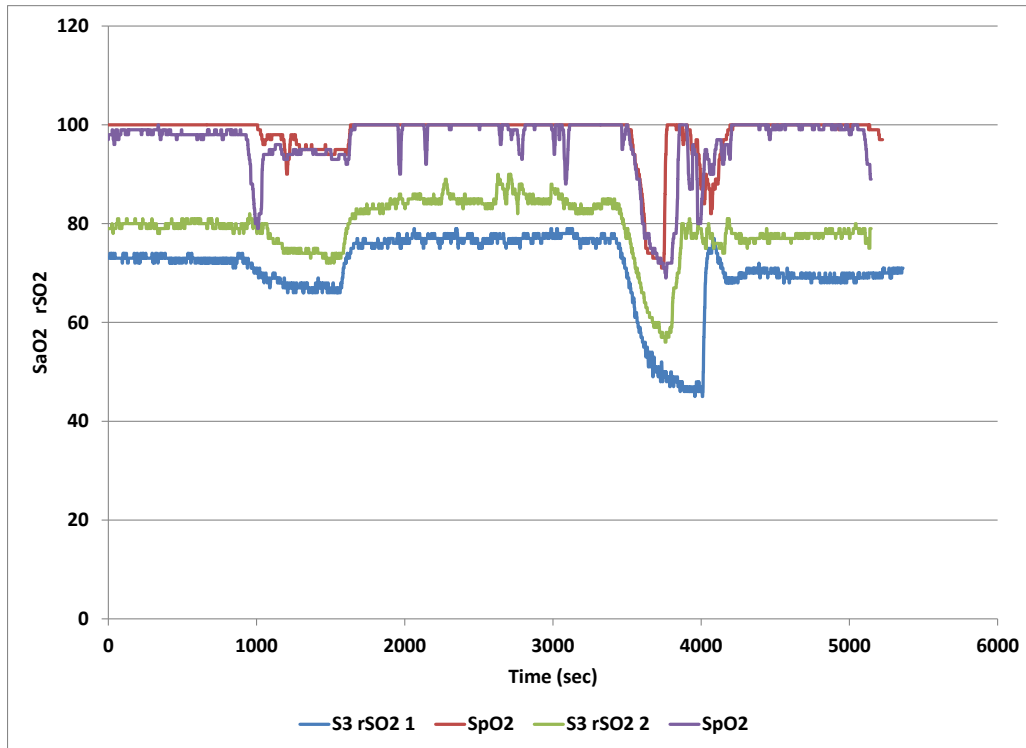






Pulse Oximeter versus NIRS at 25,000 feet



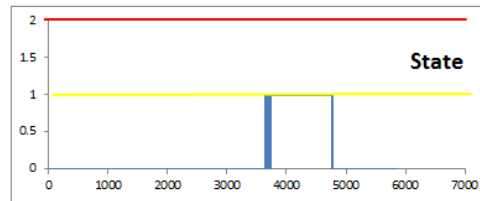
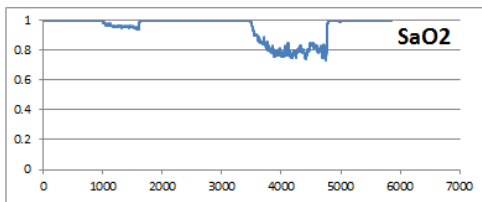
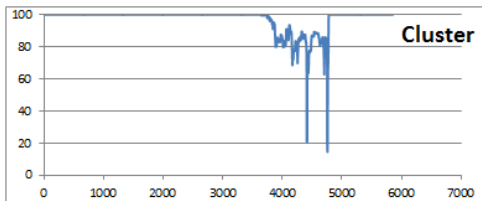
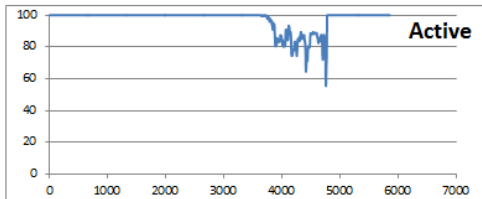




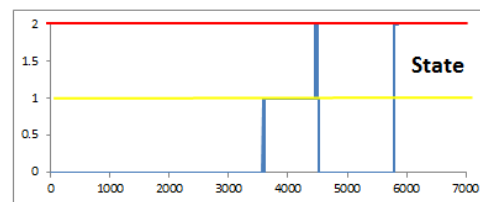
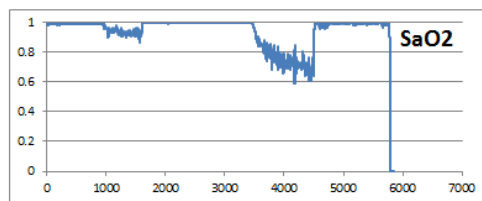
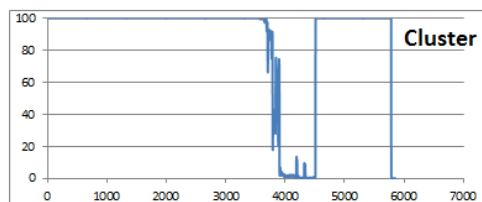
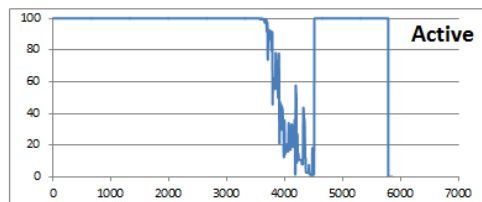
Neurological State Predictions

18K

S1 - 1

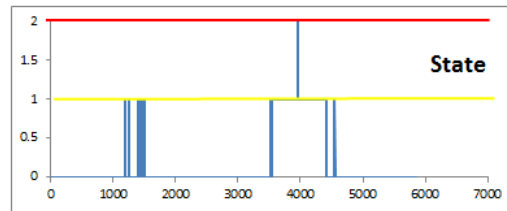
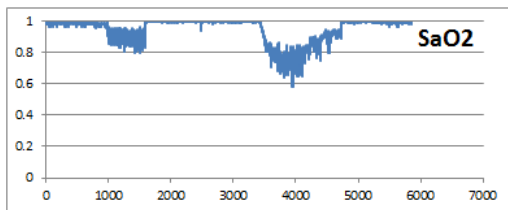
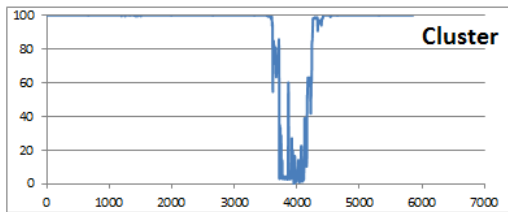
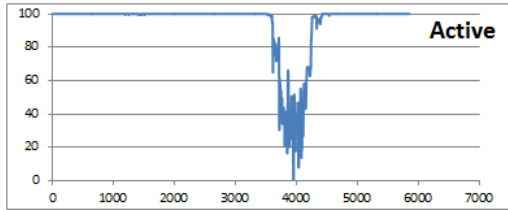


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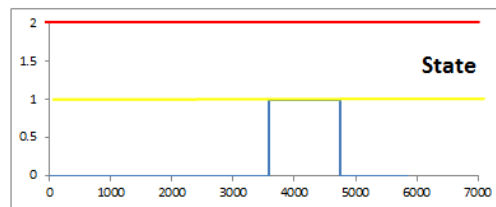
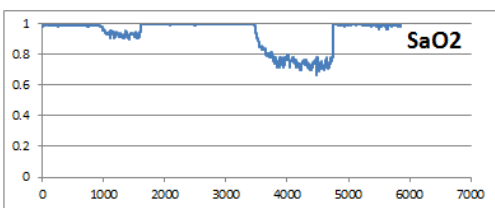
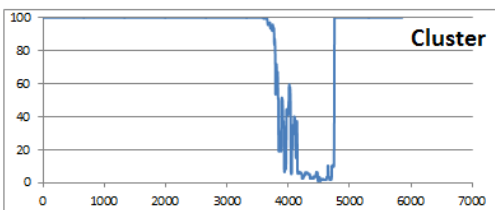
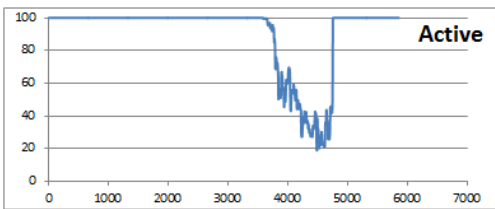




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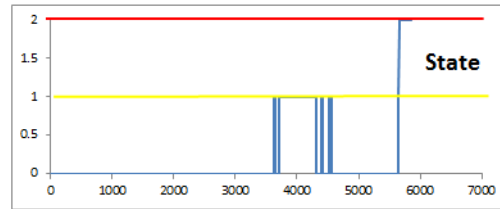
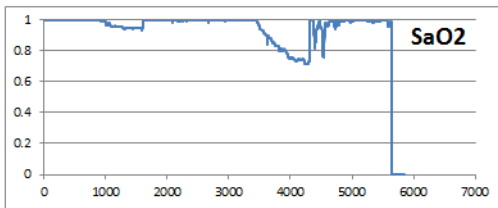
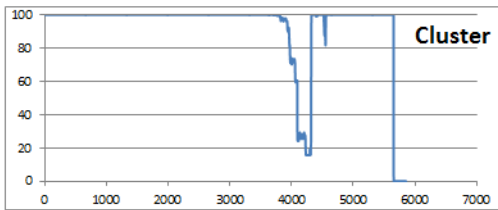
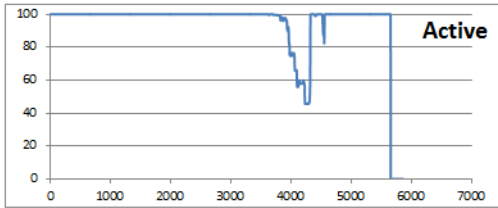


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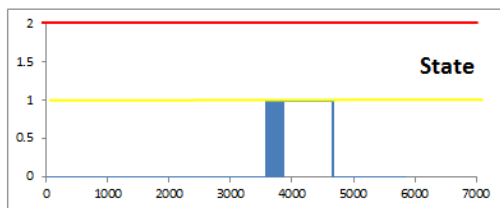
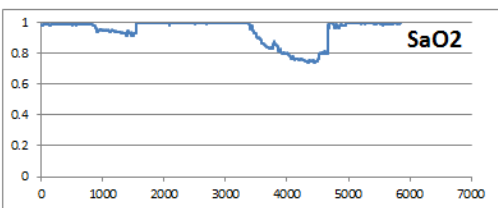
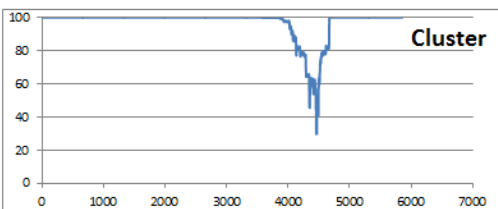
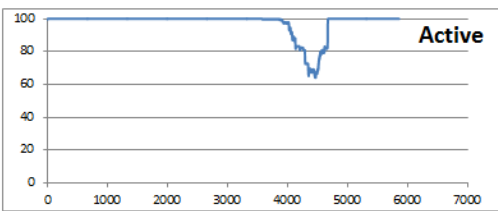




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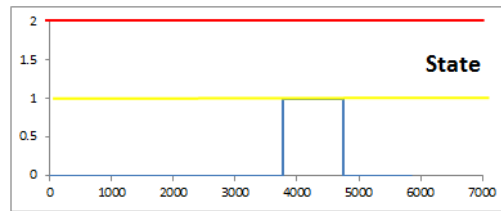
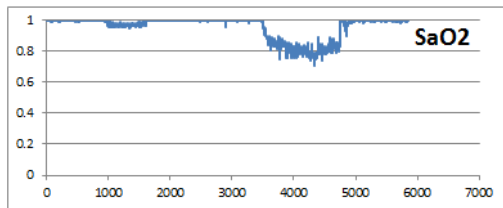
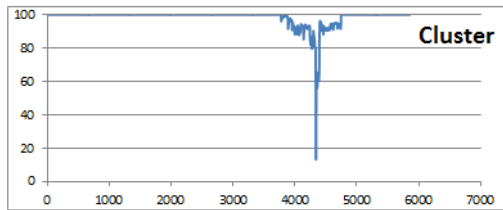
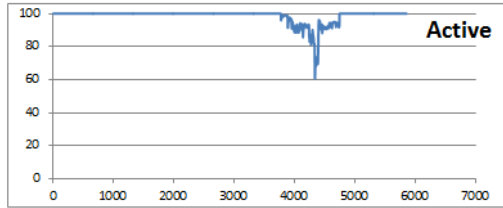


S3 - 2





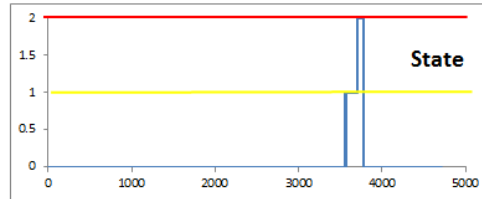
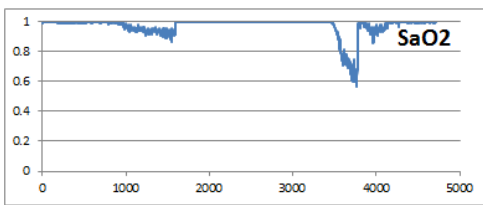
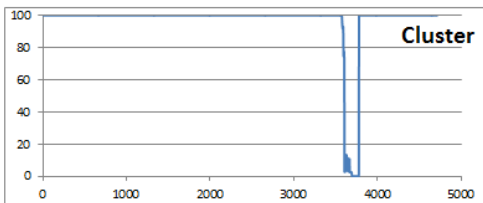
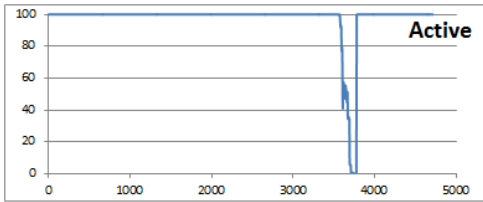
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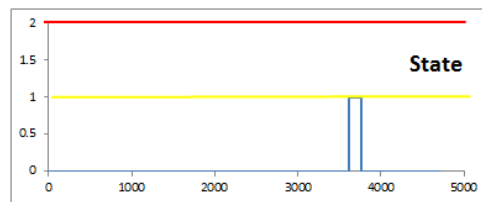
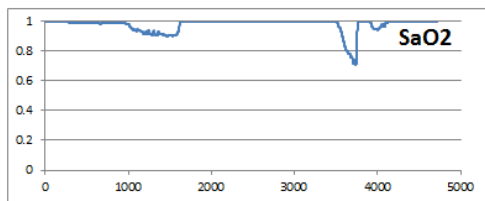
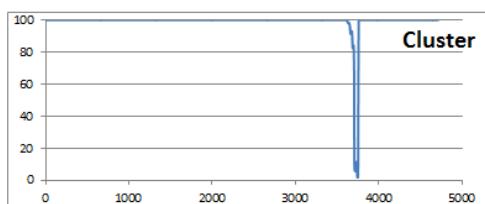
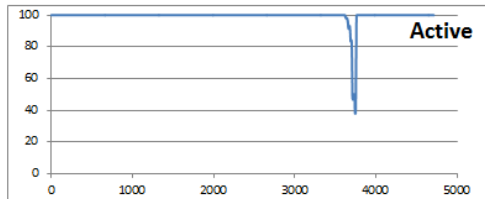


25K

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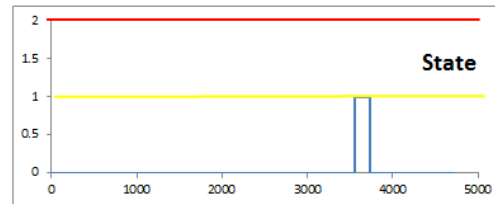
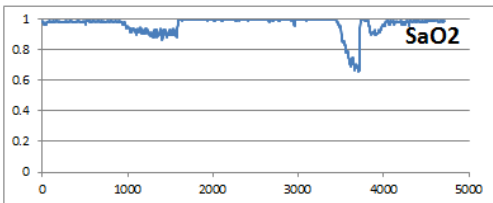
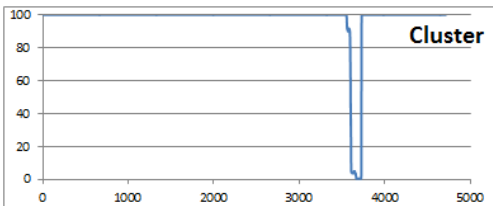
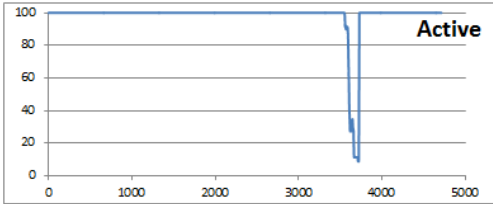


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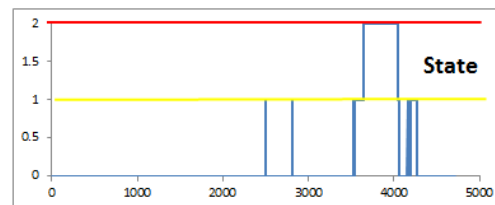
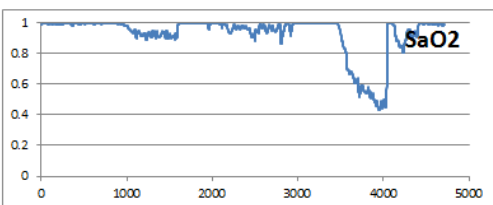
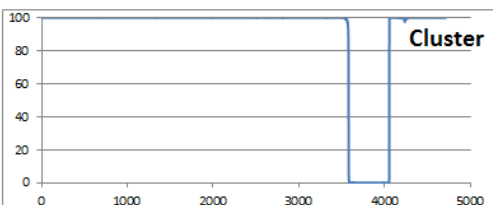
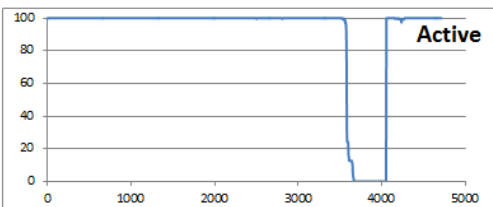




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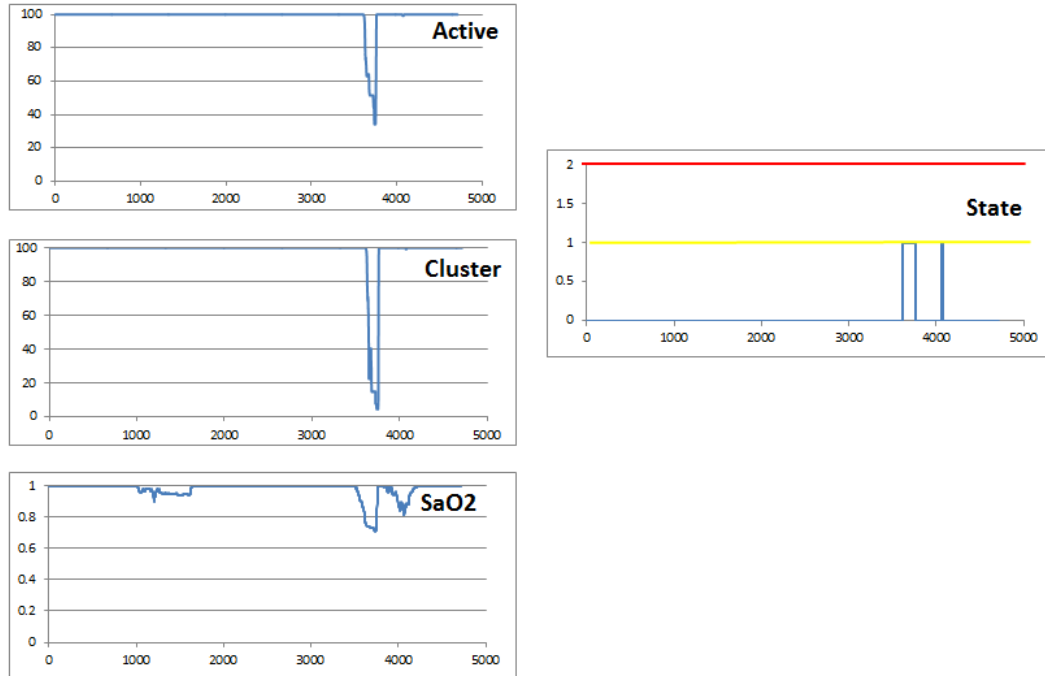


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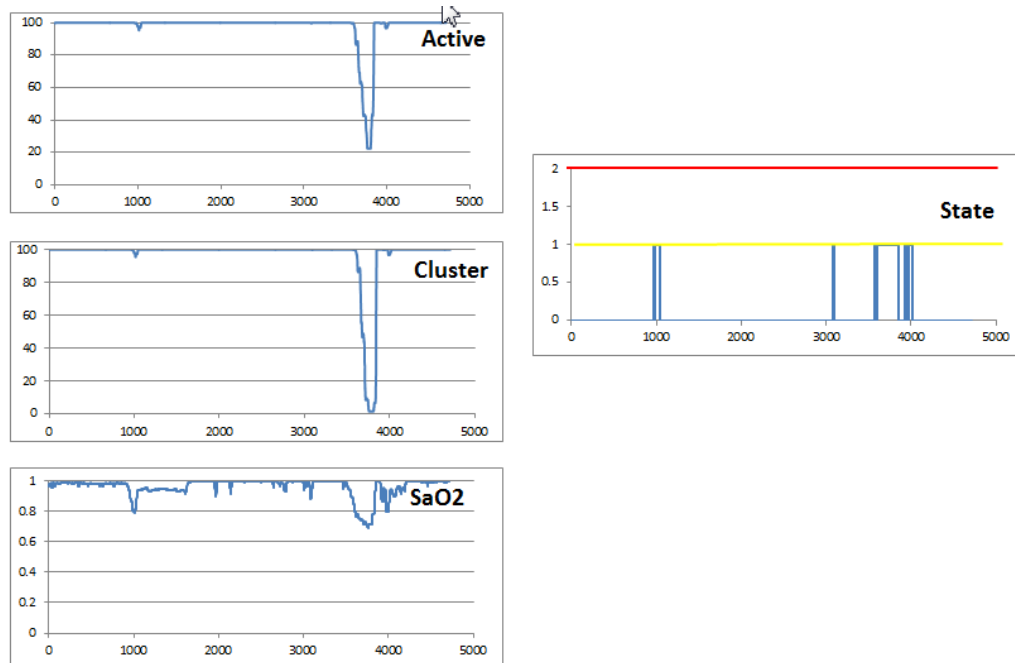




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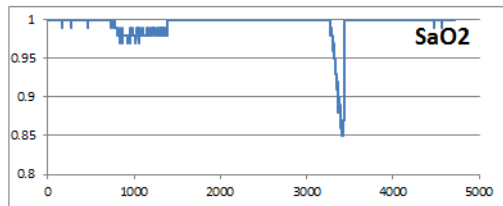
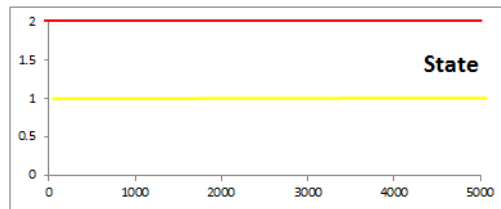
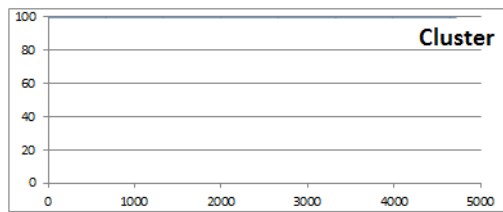
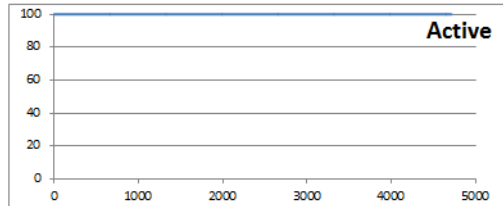


S3 - 2





S4 - 1



10.0 List of Symbols, Abbreviations and Acronyms

[O2]	Concentration of Oxygen
ADC	Analog to Digital Converter
AMS	Acute Mountain Sickness
ANS	Autonomic Nervous System
CASEVAC	Casualty Evacuation
CDR	Critical Design Review
CO	Cardiac Output
DAC	Digital to Analog Converter
DSP	Digital Signal Processing
ECG	Electrocardiogram
EVM	Evaluation Module
FDA	Food and Drug Administration
FRS	Functional Requirements Specification
ft	Feet
FTP	File Transfer Protocol
Gz	Gravitational Force from head to feet while standing upright
HAMS	Hypoxia Monitoring, Alert and Mitigation System
HRV	Heart Rate Variability
HW	Hardware
IDR	Initial Design Review
INA	Instrumentation Amplifier
LED	Light Emitting Diode
LOC	Loss of Consciousness
MDK	Medical Development Kit
NIRS	Near Infrared Spectroscopy
ONR	Office of Naval Research
OPA	Operational Amplifier
PaCO2	Alveolar Pressure of Carbon Dioxide
PaO2	Alveolar Pressure of Oxygen
PDR	Preliminary Design Review

R&D	Research and Development
RER	Respiratory Exchange Ratio
ROBD	Reduced Oxygen Breathing Device
SaO2	Arterial Oxygen Saturation Measured via CO-Oximeter
SD	Secure Digital
SDD	Software Design Description
SpO2	Arterial Oxygen Saturation Measured via Pulse-Oximeter
SRS	Software Requirements Specification
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SW	Software
TI	Texas Instruments
TUC	Time of Useful Consciousness
uPROC	Micro-Processor
USB	Universal Serial Bus
USN	United States Navy
VO2	Oxygen Consumption
WiFi	Wireless Communications
WVSM	Wireless Vital Signs Monitor



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